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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/010,317	01/21/1998	MAGNUS HOOK	TAMK:189	8522

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	29

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/010,317	HOOK ET AL.
	Examiner	Art Unit
	Robert A Zeman	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 June 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 54-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 54-59 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The amendment and response filed on 6-3-2002 is acknowledged. Claims 54-59 have been amended. Claims 54-59 are currently pending and currently under examination.

Newly amended claim 54 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: current USPTO policy limits the number of sequences recited in a given Application to one (1).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, SEQ ID NOs :12, 14-16, 21-53, 62-85, 88-102 and 105 recited in claim 54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The examination of claim 54 will be limited to SEQ ID NOs: 2, 4, 6, 8, 10, 13, 17-20, 54-55, 57, 59-61, 86 and 103-104.

Priority

The instant application is drawn to methods of generating an antibody that binds to a fibronectin-binding domain of a fibronectin binding protein and inhibits binding of said fibronectin binding protein to fibronectin. Said method comprises administering to an animal or human a peptide of a fibronectin binding protein that **does not** bind to fibronectin. Said peptides are recited as having the amino acid sequences of SEQ ID NO: 2, 4, 6, 8, 10, 13, 17-20, 54-55, 57, 59-61, 86 and 103-104. The sequences disclosed in instant application do not appear to be

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disclosed in application 60/036139. Applicant asserts that said sequences are in fact disclosed in the priority document on pages 82-85, 88, 100 and 104-105 and in Figures 1B, 2, 4A, 10A, 10B, 11A and 11B albeit with different SEQ ID NOs and in a different order. Since the absence of an ECRF in the priority document precludes an electronic (computer) comparison of said sequences and since Applicant failed to provide a correlation of the SEQ ID NOs listed in the priority document and the instant application, the filing date of the instant application will be used as the priority date. Should Applicant provide said information in the future, the effective priority will be reassessed as appropriate.

Objections Withdrawn

The objection to the disclosure for reciting incomplete ATCC accession numbers is withdrawn in light of the amendment thereto.

The objection based the apparent disclosure of the same sequence in SEQ ID NO:3 and SEQ ID NO:4 as well as SEQ ID NO9 and SEQ ID NO:10 is withdrawn. Applicant's argument has been fully considered and deemed persuasive.

Claim Objections Withdrawn

The objection to claims 55-59 for the improper use of articles is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claims 57- 58 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “positive candidate peptide” is withdrawn in light of the amendment thereto.

The rejection of claim 57 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “dispersing” is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-59 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 54 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “consists essentially of” is maintained for reasons of record.

Applicant argues:

1. Other patents have issued using the “consisting essentially of” language.

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2. The “basic and novel characteristics” are the fact that the specific peptide does not bind to fibronectin and that the generation of antibodies thereto will be useful in preventing bacteria from binding fibronectin and thus can used to treat or protect against bacterial infection.

Applicant’s arguments have been fully considered and deemed non-persuasive. As outlined in the previous Office action the “consisting essentially of” language is unclear in the context of a polypeptide sequence. The use and meaning of “consisting essentially of” is well established with regard to **compositions**. Said phrase allows the addition of other ingredients or elements that do not affect the properties of the composition. It is not possible to know what sequences or other material can be added to the recited polypeptides that would not materially affect the nature of that polypeptide sequence.

In response to applicant's argument that “basic and novel characteristics” are known, it is noted that the features upon which applicant relies (i.e., “basic and novel characteristics” are the fact ... **that the generation of antibodies thereto will be useful in preventing bacteria from binding fibronectin and thus can used to treat or protect against bacterial infection.**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to Applicant’s argument that the aforementioned language has been used in other patents, Applicant is reminded that each application is examined on the basis of its own merits and the prosecution of one application does not affect the prosecution of another.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant application is drawn to methods of generating an antibody that binds to a fibronectin-binding domain of a fibronectin binding protein and inhibits binding of said fibronectin binding protein to fibronectin. Said method comprises administering to an animal or human a peptide of a fibronectin binding protein that **does not** bind to fibronectin. Said peptides are recited as having the amino acid sequences of SEQ ID NO: 2, 4, 6, 8, 10, 13, 17-20, 54-55, 57, 59-61, 86 and 103-104.

The rejection of claims 54-59 under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (*Infection and Immunity*, Vol. 65, No. 2, 1997 pages 537-543—IDS-5) is maintained for reasons of record.

Applicant argues that the cited reference is not prior art since it was published after the filing date of the priority document.

Applicant's arguments have been fully considered and deemed non-persuasive. Applicant is reminded that the filing date of the instant application is the priority date of the instant application until and unless the basis for granting priority as of the filing date of 60036,139 for each sequence now being examined is established on the record.

The rejection of claims 54-59 under 35 U.S.C. 103(a) as being unpatentable over Hook et al. (WO 92/02555—IDS-5) is maintained for reasons of record.

Contrary to Applicant's assertion Hook et al. disclose peptides/proteins with the amino acid sequences of SEQ ID NO: 61 and 104 (see abstract and page 4 lines 16-36) and that said peptides could be used to generate antibodies (see page 16). Hook et al. further disclose that said antibodies were capable of inhibiting fibronectin binding. As outlined in the previous Office action, Hook et al. et al. differs from the instant invention in that they do not explicitly disclose that peptides used were unable to bind fibronectin. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. It should also be noted that the instant claims recite "consists essentially of" which is "open" claim language. Consequently the claims, in absence of evidence to the contrary, also read on the entire fibronectin binding protein or any fragments thereof.

The rejection of claims 54-59 under 35 U.S.C. 103(a) as being unpatentable over Hook et al. (US 5,440,014—IDS-5) is maintained for reasons of record.

Applicant argues:

1. Hook et al. do not disclose SEQ ID NO:61 or 103.
2. Hook et al. do not disclose methods using peptides for the generation of antibodies.

Applicant's arguments have been fully considered and deemed non-persuasive.

Contrary to Applicants assertion, Hook et al. disclose peptides/proteins with the amino acid sequences of SEQ ID NO: 61 and 104 (see figure 1 and column 2, line 57-69) **and that said peptides could be used to generate antibodies (see abstract)**. Hook et al. further disclose that said antibodies were capable of inhibiting fibronectin binding. As outlined in the previous Office action, Hook et al. et al. differs from the instant invention in that they do not explicitly disclose that peptides used were unable to bind fibronectin. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. It should also be noted that the instant claims recite “consists essentially of” which is “open” claim language. Consequently the claims, in absence of evidence to the contrary, read on the entire fibronectin binding protein or any fragments thereof.

The rejection of claims 54-59 under 35 U.S.C. 103(a) as being unpatentable over Huff et al. (*Journal of Biological Chemistry*, Vol. 269, No. 22, 1994, pages 15563-15570—IDS-5) is maintained for reasons of record.

Applicant argues:

1. Huff et al. do not disclose SEQ ID NO:61 or 103.
2. Huff et al. do not disclose methods using peptides for the generation of antibodies.

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Applicant's arguments have been fully considered and deemed non-persuasive.

Contrary to Applicant's assertion, Huff et al. disclose both SEQ ID NO:61 and 103 (see Figure 1). As outlined in the previous Office action, Huff et al. et al. differs from the instant invention in that they do not explicitly disclose that peptides used were unable to bind fibronectin or that said peptides could be used to generate antibodies. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. Additionally, it would have been obvious to one of the skill in the art to use said peptides to generate antibodies. Finally, it should also be noted that the instant claims recite "consists essentially of" which is "open" claim language. Consequently the claims, in absence of evidence to the contrary, read on the entire fibronectin binding protein or any fragments thereof.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
August 7, 2002